Valentine International Ltd.
詠 立 實 業 有 限 公 司
E-mail : info@valentine-dynalife.com.tw
http : // www.valentine-dynalife.com
Tel:886-2-8692-6662
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"510(k) SUMMARY"

MAY 2 8 2014

K130017

Submitter's Name: Valentine International Ltd.
8F, No. 149, Sec. 2, Ta Tung Rd., Hsichih District, New Taipei City, 221, Taiwan, R.O.C.

Date of summary prepared: December 31, 2013

Device Name:

Proprietary Name: Valentine Steel Wheelchair, model: 1000

Common or Usual Name: Mechanical Wheelchair

Classification Name: Mechanical Wheelchair, Class I, 21 CFR 890.3850

510K contact person for all correspondence

Dr. Jen, Ke-Min
Tel: 886-3-5208829 Fax: 886-3-5209783
Email: ceirs.jen@msa.hinet.net

Indications for Use:

The device is intended for medical purpose to provide mobility to persons restricted to a sitting position.

Description of the device:

The Valentine Steel Wheelchair, model: 1000 is an indoor / outdoor wheelchair that has a base with four-wheeled with a seat. The device can be disassembled for transportation and it is foldable easily. The device is consistent with the ISO 7176 series standards and uses a standard sling type back and seat, and the upholstery fabric meets the flame retardant test.

The maximum weight bearing capacity of the device is 250 lbs/113.5 kgs. The following surfaces are recommended not to operate on:

- Sand surface
- Wet or icy surface
- Road maintenance hole metal cover
- Multiple steps.
- Escalators. (Use the elevator.)
- Steep incline over 10 degrees.
- Ground clearance over 60 mm / 2.3"
- Curb climbing ability over 20 mm / 0.8"

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Legally marketed device for substantial equivalence comparison:

Zhenjiang Assure Mechanical Wheelchair, model: A227 (K112816)

Performance Testing:

Valentine Steel Wheelchair, model: 1000 meets the applicable performance requirements as specified in ANSI/RESNA WC vol. 1 and ISO 7176 Wheelchair Standards.

Technological Characteristics Summary:

To ensure the safety and effectiveness of the device, the following ISO standards were complied with:

- ISO7176-1:1999, Wheelchairs - Part 1: Determination of Static Stability.
- ISO7176-3: 2012, Wheelchairs - Part 3: Determination of effectiveness of brakes.
- ISO7176-5: 2008, Wheelchairs - Part 5: Determination of overall dimensions, mass and maneuvering space.
- ISO7176-7: 1998, Wheelchairs - Part 7: Measurement of seating and wheel dimensions.
- ISO7176-8: 1998, Wheelchairs - Part 8: Requirements and test methods for static, impact and fatigue strengths.
- ISO7176-11:2012, Wheelchairs - Part 11: Test dummies.
- ISO7176-13:1989, Wheelchairs - Part 13: Determination of coefficient of friction of test surfaces.
- ISO7176-15:1996, Wheelchairs - Part 15: Requirements for information disclosure, documentation and labelling.
- ISO7176-16:2012, Wheelchairs - Part 16: Resistance to ignition of upholstered parts, Requirements and test methods.

Discussion of Clinical Testing Performed:

NA

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Comparison Table between the subject device and predicate device:

ITEMS	PREDICATE DEVICE	SUBJECT DEVICE
BRAND NAME	**Zhenjiang Assure**	**Valentine**
MANUFACTURER	Zhenjiang Assure Medical Equipment Co., Ltd.	Valentine International Ltd.
MODEL NO	**Mechanical Wheelchair, A227**	**Steel Wheelchair, model 1000**
510K NO	**K112816**	**K130017**
INTENDED USE	The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.	Same
OPERATING	Indoor / outdoor wheelchair	Same
TECHNOLOGICAL CHARACTERISTICS	According to ISO 7176-1/-3/-5/-7/-8/-11/-13/ -15/-16 series standards	Same
FRAME **Seat width** **Cross brace** **Seat height** **Backrest height** **Reclining backrest** **Seat sling** **Frame colors**	 18” YES 20” un-adjustable fixed padded nylon Blue	Same
ARMREST **Arm pad** **Flip back** **Height-adjustable**	 Padded YES, detachable Pre-installed armrests	Same
HANGERS **Swing-away** **Elevating leg rest** **Articulating leg rest** **Footplate style** **Heel loop** **Footrest angle**	 YES YES YES Padded No $10\sim15^0$	Same
REAR AXLE **Offset axle** **Quick-release axle**	 YES YES	Same

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ITEMS	PREDICATE DEVICE	SUBJECT DEVICE
REAR WHEEL **Size** **Tire type** **Handrim material**	 24" PU solid material Steel composite	Same
CASTERS **Size** **Tire type**	 8" PU solid material	Same
WHEEL LOCK	Pull-to-Lock	Same
WEIGHT CAPACITY	250 lbs/113.5 kgs	Same
WEIGHT OF CHAIR	40 lbs / 18.2 kgs	Same
WARRANTY	12 months for the main parts (The chair side frames are guaranteed for 5 years from the date of purchase.)	Same
ACCESSORIES **Anti-tipper** **Rear stepper** **Fold down push handle** **Safety belt**	 YES YES YES Optional	 NO YES YES Optional

※ Actually, the subject device is identical to and transferred from the predicate device.

Substantial equivalence comparison discussion:

Actually, the subject device is identical to and transferred from the predicate device. From the above comparison table the intended uses between the subject device: Valentine Steel Wheelchair, model: 1000 and the predicate device: Zhenjiang Assure Mechanical Wheelchair, model: A227 (K112816) are the same. Mainframes of two devices are foldable. There are similar removable desk-length armrest and same swing-away detachable elevating footrest. Besides, back upholstery material is also the same resistance-ignitability fabric and also meets the requirements for flame retardant. The differences in the overall appearance do not raise any safety or effectiveness aspect. Thus the subject device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 28, 2014

Valentine International, Limited
Dr. Jen, Ke-Min
8F, No. 149, Sec. 2, Ta Tung Rd.,
Hsichih District - New Taipei City 221
Taiwan. R.O.C.

Re: K130017
Trade/Device Name: Valentine Steel Wheelchair, model: 1000
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: April 6, 2014
Received: April 15, 2014

Dear Dr. Jen, Ke-Min:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K130017

Device Name
Valentine Steel Wheelchair, model: 1000

Indications for Use *(Describe)*
The device is intended for medical purpose to provide mobility to persons restricted to a sitting position.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Felipe Aguel -S Date: 2014.05.28 17:26:40 -04'00'

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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